Handouts for Presentation by
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Public Forum on
Protein Derived from Ruminants and Mink in Ruminant Feeds
Environmental Impact of Proposed Rule and Alternatives
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FDA has carefully considered the potential environmental effects of this proposed rule and of five possible alternative actions. In doing so, the agency reviewed ANPRM comments submitted by a number of organizations and individuals. Comments were mostly concerned with the amounts of 4-D animals and offal that would be affected and the means by which they could be disposed of or utilized safely. Besides feeds for non-ruminants, non-feed uses such as fertilizers and disposal methods such as on-farm burial, landfilling, and incineration were addressed.

The decisionmaking process that led to this proposed rule has been characterized by the careful consideration of a spectrum of possible actions that the FDA could take. In the environmental assessment that accompanies this proposed rule, the FDA evaluated the environmental consequences of six different potential actions that cover this spectrum. See Table 1. These potential actions were termed Option 1--watchful waiting, Option 2--adult sheep and goat-derived protein restrictions, Option 3--sheep, goat, elk, deer and mink-derived protein restrictions, Option 4-- ruminant and mink-derived protein to ruminant ban (The Proposed Action), Option 5--ruminant and mink designated tissue ban, and Option 6--mammalian-derived protein to ruminant ban. The environmental consequences that were examined included on-farm burial, disposal in landfills and by incineration, TSE exposure to wildlife, impacts due to production losses in animals, and the amount of industry wastes produced. See Figures.

Due to the numerous uncertainties associated with the TSEs, the environmental assessment only attempts to make a qualitative estimate of the environmental consequences. Two scenarios were considered: 1) the impacts if BSE does not occur in the US (which are also the immediate impacts of choosing and implementing an Option), and 2) the impacts if BSE occurs in the US after an Option is implemented. The later are termed long term impacts as they would take a number of years to occur and the impacts would last until BSE was successfully eradicated, as much as 15-20 years if the experience in the United Kingdom is a guide.

Under Scenario 1, using Option 1 as the “no action” baseline comparison, the FDA believes that the immediate impact of the other five potential actions will range from a slight to moderate increase in the disposal of carcasses via on-farm burial, landfilling and incineration. It is also possible that a slight to moderate increase in the landfilling and incineration of slaughter, rendering and feed manufacturing wastes will occur with the five potential actions. Increases in waste disposal are anticipated to be temporary, however, as the markets are expected to adjust quickly to the more restricted uses of the ruminant material.

If the actions taken by the renderers, feed producers and ruminant producers, the combined actions of state and federal government agencies, and the interplay of risk factors for the United States all result in BSE not occurring in the US, then Scenario 1 impacts are also the long term impacts of the Options considered. There would be no expected changes in the exposure of wildlife to TSE agents and there would be no effect on current production losses from these diseases in the US.

Under Scenario 2, on the other hand, it is assumed that BSE will occur in the long term in this country in spite of our combined efforts, or that BSE is already present undiagnosed. The various options would be expected to have a range of environmental impacts that would depend upon the extent of spread of BSE that occurred before diagnosis. The worst spread of BSE would be expected to occur under Option 1--Watchful Waiting. Options 2 and 3 would be expected to be about the same as Option 1 if BSE occurred, they only attempt to reduce the probability of a TSE cross-over from other species. Under this scenario, the environmental consequences from Options 4 and 6 would be anticipated to be minimal in comparison

to Option 1, 2 and 3 as they should prevent amplification of BSE through feed in all ruminants, especially cattle. Option 5, a designated tissue restriction, is harder to comply with than Options 4 and 6 and there are uncertainties about whether all the potentially infective tissues have been identified. Therefore, it was concluded that Option 5 would not be quite as effective in preventing the spread of BSE through ruminant feed ingredients compared to Options 4 and 6.

In sum, if one expects BSE to occur in the US for any reason, Options 4 and 6 would appear to be environmentally preferable, as they would minimize the number of animals affected and the consequences of disposing of them and all feed products potentially containing proteins derived from them. Options 4 and 6 would also minimize on-farm exposures of wildlife to BSE before and during disposal of BSE-affected animals.

The agency has concluded that the proposed rule will not have a significant impact on the human environment, and that an environmental impact statement is not required. FDA's finding of no significant impact (FONSI) and the evidence supporting that finding, contained in an environmental assessment (EA) prepared under 21 CFR 25.31, may be seen in the dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. An electronic version of the environmental documents may be seen and obtained from the CVM Home Page on the World Wide Web at **http://www.cvm.fda.gov**. FDA invites comments and submission of data concerning the EA and FONSI.

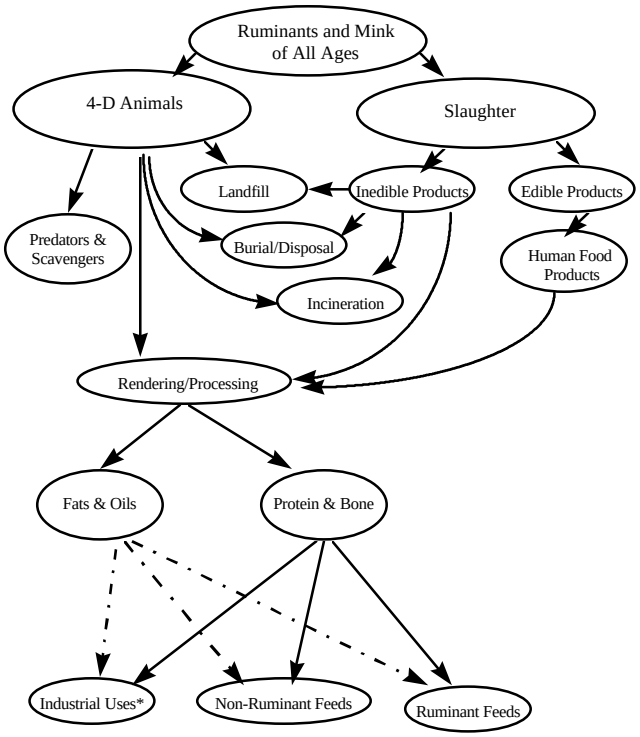
Table 1. Comparison of the Environmental Effects Associated with Potential Actions.

Environmental Effects	**Potential Actions**					
	Watchful Waiting	**Adult Sheep & Goat Controls**	**Sheep,Goat, Deer, Elk & Mink Controls**	**Ruminant Protein to Ruminant Ban**	**Designated Tissues Ban**	**Mammalian Protein to Ruminant Ban**
Immediate Impacts						
On-Farm Disposal	No Changes	Slight Increase	Slight Increase	Moderate Increase	Moderate Increase	Moderate Increase?
Landfill	No Changes	Slight Increase	Moderate Increase	Moderate Increase	Moderate Increase	Moderate Increase?
Incineration	No Changes	No Changes	Slight Increase	Slight Increase	Slight Increase	Slight Increase?
Industry Wastes Produced	No Changes	Slight Increase	Slight Increase	Slight Increase	Moderate Increase	Moderate Increase?
Probability of BSE Occurring in US	Minimum Effect	Some Reduction	Moderate Reduction	Near Maximum Reduction	Very High Reduction	Maximum Reduction

Table 1. Comparison of the Environmental Effects Associated with Potential Actions (continued).

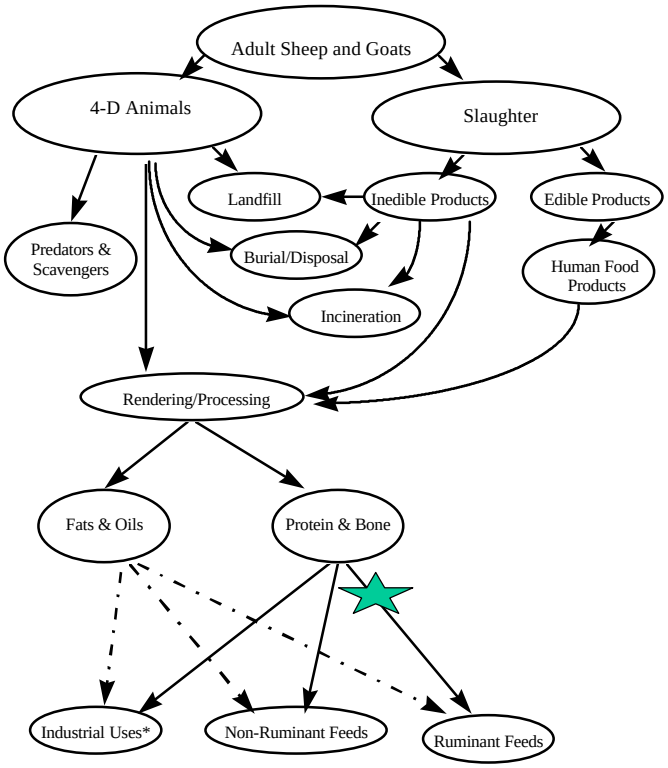
Environmental Effects	Potential Actions (Continued)					
	Watchful Waiting	**Adult Sheep & Goat Controls**	**Sheep,Goat, Deer, Elk & Mink Controls**	**Ruminant Protein to Ruminant Ban**	**Designated Tissues Ban**	**Mammalian Protein to Ruminant Ban**
Consequences if BSE Occurs Long Term						
Production Losses & Impacts	Maximum Losses	Maximum Losses	Maximum Losses	Minimum Losses	Near Minimum Losses	Minimum Losses
Wildlife Exposure	Maximum Exposures	Maximum Exposures	Maximum Exposures	Minimum Exposures	Small Increase	Minimum Exposures
On-Farm Disposal	Largest Increase	Largest Increase	Largest Increase	Minimum Increase	Small Increase	Minimum Increase
Landfill	Largest Increase	Largest Increase	Largest Increase	Minimum Increase	Small Increase	Minimum Increase
Incineration	Largest Increase	Largest Increase	Largest Increase	Minimum Increase	Small Increase	Minimum Increase

Figure 1. Disposition Patterns for Ruminants and Mink in the US - Option 1.



*includes, but is not limited to, fertilizers and lubricants.

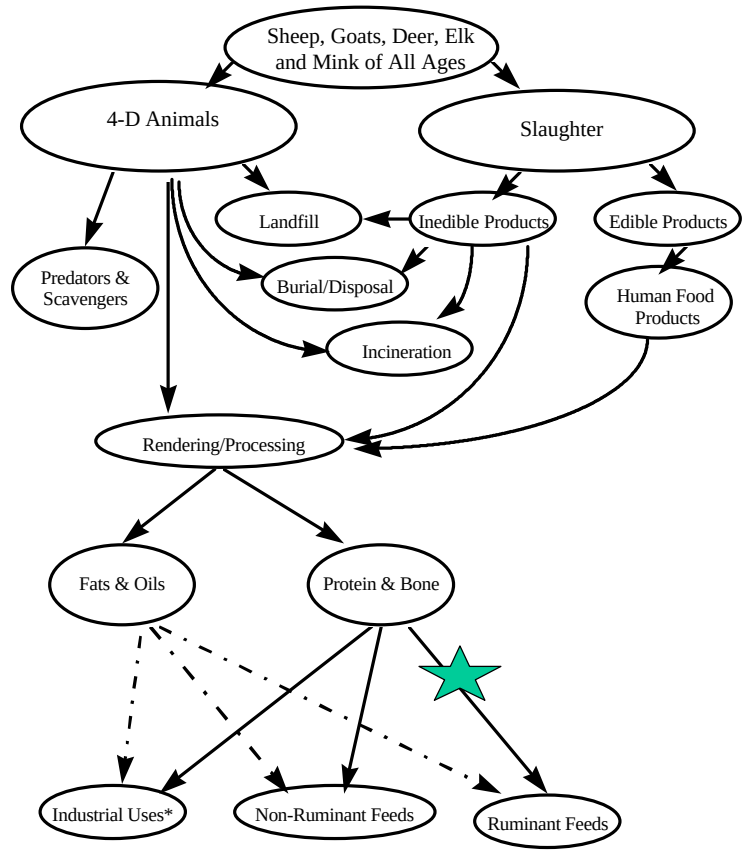
Figure 2. Disposition Patterns for Adult Sheep and Goats in the US - Option 2.



*includes, but is not limited to, fertilizers and lubricants.

☆ pathway partially blocked, some proteins from adult sheep & goats permitted in ruminant feeds.

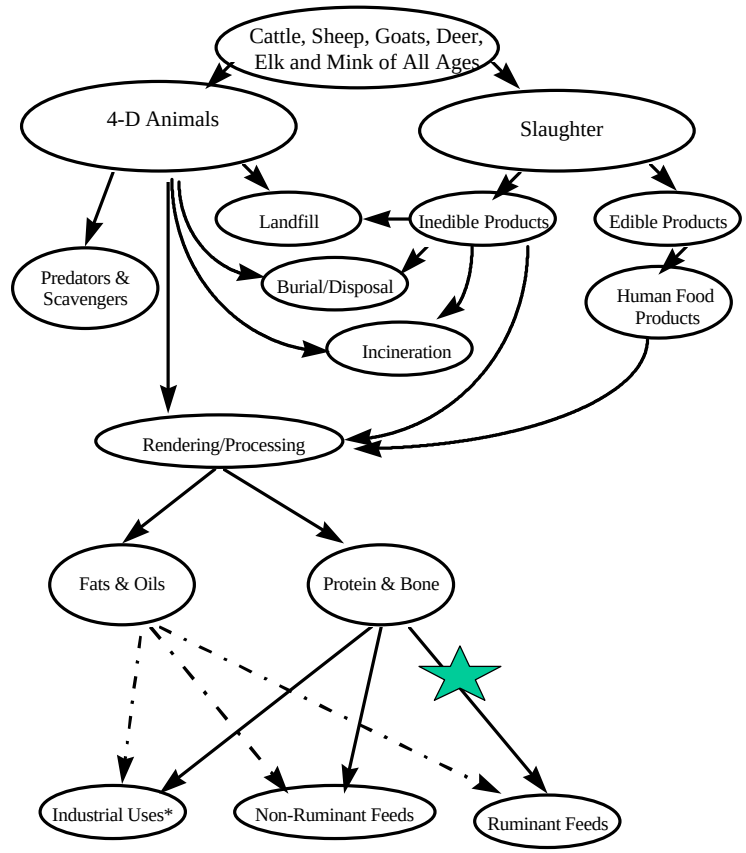
Figure 3. Prohibit Proteins from Sheep, Goats, Deer, Elk and Mink in Ruminant Feeds in the US - Option 3.



* includes but is not limited to fertilizers and lubricants.

★ pathway partially blocked, milk products and gelatin from identified species are permitted in ruminant feeds.

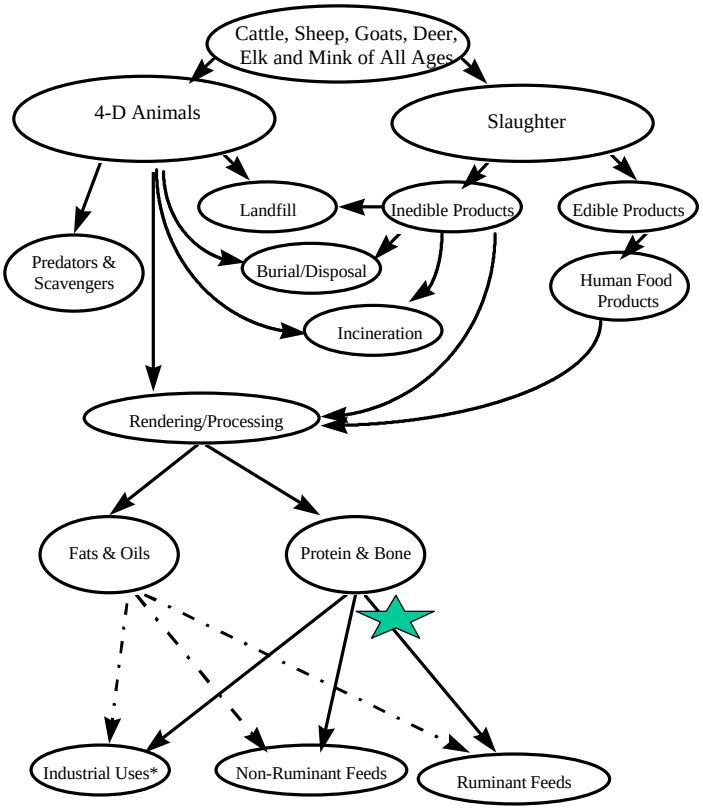
Figure 4. Prohibit Proteins Derived from Ruminants and Mink in Ruminant Feeds in the US - Option 4.



* includes but is not limited to fertilizers and lubricants.

pathway partially blocked, milk products and gelatin from ruminants and bovine blood products permitted in ruminant feeds.

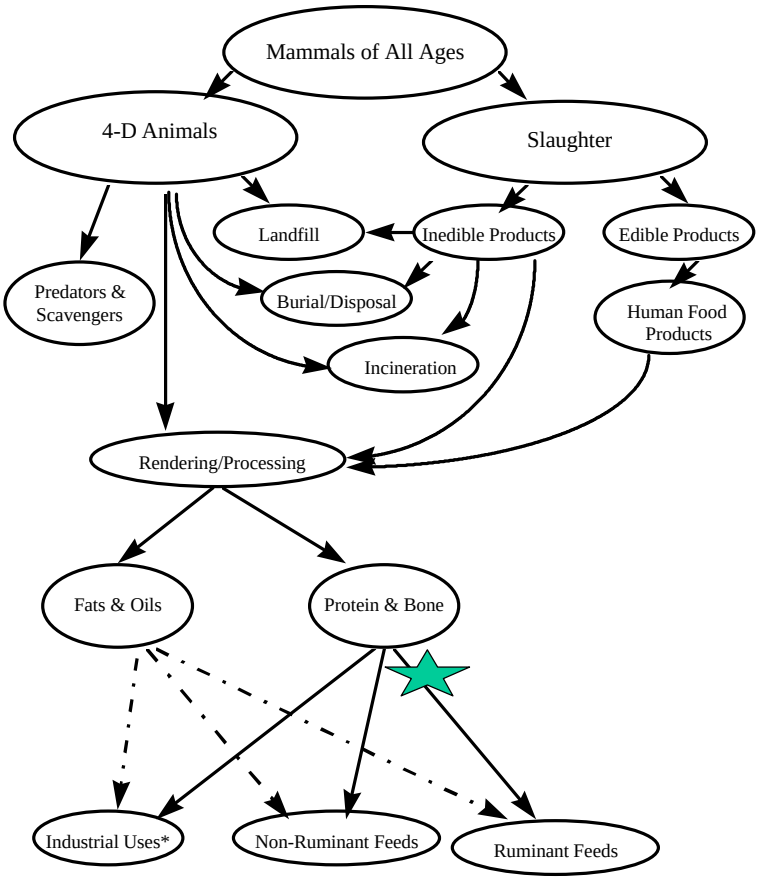
Figure 5. Disposition Patterns for Proteins Derived from Designated Tissues - Option 5



* includes but is not limited to, fertilizers and lubricants.

☆ pathway partially blocked, some protein products from non-4-D bovine, bovine blood products and milk products and gelatin from bovine, ovine, caprine and cervine are permitted in ruminant feeds.

Figure 6. Disposition Patterns for Mammals in the US - Option 6 Mammalian Protein to Ruminant Feed Prohibition



* includes but is not limited to, fertilizers and lubricants.

☆ pathway partially blocked, milk products and gelatin are permitted in ruminant feeds.